

SEP 10 1996

K 960875

510(k) NOTIFICATION

Sigma Diagnostics
545 South Ewing Avenue
St. Louis, MO 63103

KC 40 Micro
Coagulation Analyzer
February 27, 1996

ATTACHMENT 1

510(k) Summary of Safety and Effectiveness

The Amelung KC 40 Micro Coagulation Analyzer is an automated random access multipurpose analyzer. The KC 40 can be used for the detection of fibrin formation utilizing mechanical principles (ball method) to perform clot based tests such as prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen, factor assays, and other clotting tests.

In comparison studies between the KC 40 and the TOA Medical Electronics CA-5000, the following regression statistics were obtained:

PT	$r = 0.980$	$y = 1.123x + 0.616$
APTT	$r = 0.936$	$y = 1.101x + 4.570$
Fibrinogen	$r = 0.931$	$y = 1.163x - 29.927$
Factor IX	$r = 0.944$	$y = 0.964x + 7.937$
Factor X	$r = 0.970$	$y = 1.040x - 1.884$

In comparison studies between the KC 40 and the BBL Fibrometer, the following regression statistics were obtained:

PT	$r = 0.980$	$y = 1.009x + 0.701$
APTT	$r = 0.915$	$y = 1.244x - 0.778$

The coefficient of variation for precision studies was less than 5% for the PT and APTT assays, less than 6% for the fibrinogen assay, and less than 10% for the factor assays.

The safety and effectiveness of the KC 40 Micro Coagulation Analyzer is demonstrated by its substantial equivalency to the predicate devices.